

## **Patient Brochure**

### **Cordis PRECISE® Nitinol Stent System ANGIOGUARD™ XP Emboli Capture Guidewire**

#### **A Patient's Guide to-Disease in the Carotid Arteries**

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This guidebook is provided as a courtesy from Cordis Corporation intended to help you learn more about carotid artery disease.

For your convenience, a glossary of medical terms is included at the end of this booklet. Words that are in bold throughout the text are defined in the glossary.

This booklet is only a guideline. It provides basic information about carotid artery disease and its treatment with the Cordis PRECISE Nitinol **Stent** System and the ANGIOGUARD XP **Emboli** Capture Guidewire. It is not intended to diagnose a medical condition. The treatment of carotid artery disease may vary according to each individual's unique needs and doctor assessments. As with any medical procedure, the best source for information and advice is your doctor

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## INTRODUCTION

This guidebook is designed to help you and your family to understand vascular disease of the **carotid arteries** of your neck and treatment with a vascular **stent**. If you have any questions as you read, please write them down and discuss them with your doctor or nurse.

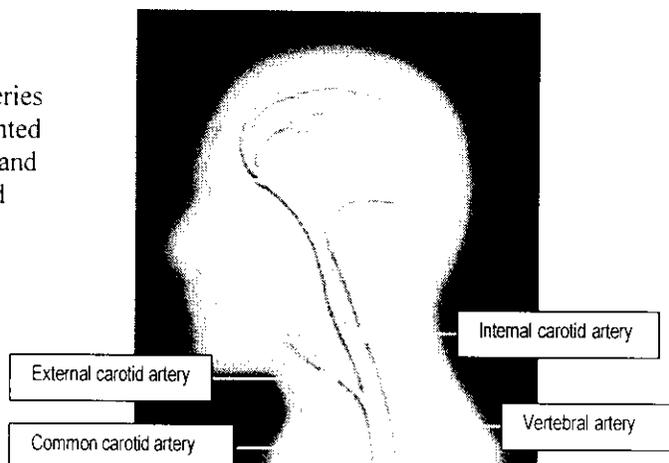
## VASCULAR DISEASE IN CAROTID ARTERIES OF THE NECK

Vascular disease is caused by the build-up of fatty substances that collect and stick to the linings of your arteries, in a process known as **atherosclerosis**. You may also hear the terms "**plaque**", "blockage", "**lesion**", or "**stenosis**". As the **plaque** build-up continues, the internal lining of your artery thickens which causes the artery to narrow and limit blood flow to vital tissues and organs. Some of the more commonly affected arteries are those located in the legs, arms, neck and kidneys. The symptoms from these blockages depend on what artery is affected and the severity of the blockage causing limited blood flow. This guidebook describes peripheral vascular disease of the arteries in your neck, which are called *carotid arteries*.

## THE CAROTID ARTERIES

**FUNCTION** - Arteries are vessels that carry blood away from the heart. The **carotid arteries** extend from the main artery (aortic arch) coming directly from your heart and supply oxygen-rich blood to the brain.

The carotid arteries that may be stented are the internal and common carotid arteries.



**CAROTID ARTERY NARROWING (STENOSIS)** - When **plaque** builds up in the **carotid arteries**, they begin to narrow and blood flow to the brain. This is called carotid artery **stenosis**. Severe carotid artery **stenosis** is a major cause of stroke.

**DIAGNOSIS** - You should be screened for carotid artery **stenosis** if you have:

- Weakness, numbness, tingling or paralysis of the arm, leg or face on one side of your body
- Trouble swallowing
- Loss of eyesight or blurry eyesight in one eye
- Dizziness, confusion, fainting or coma
- Unexplained slurred or garbled speech

Sometimes, patients are screened for carotid artery **stenosis** if the doctor knows the patient has vascular disease elsewhere in the body. Blockages can also be found when your physician hears a sound through a stethoscope placed on the neck. The sound is caused by blood flowing past the blockage.

The following tests may be performed if carotid artery disease is suspected.

**Carotid artery ultrasound:** This test uses soundwaves that produce an image of **carotid arteries** onto a TV screen, and can be helpful in identifying narrowing in the **carotid arteries**. This test is painless and does not require the use of needles, dye, or x-rays.

**Angiography:** An **angiogram** uses x-rays to take a picture of your carotid artery. In order for the x-ray to 'see' your arteries, a dye is injected through a small tube (**catheter**) inserted into an artery in the groin or arm. This procedure will determine exactly where the narrowing is located and will help to guide further treatments. You will be awake for the test, although you will be given a light sedative to relax you. The injection of dye may cause a warm sensation. After the test is complete you will need to lie flat for 5-6 hours to allow the puncture site in your groin or arm to heal.

### **TREATMENT OPTIONS**

It is important to inform your doctor about your entire medical history. Be sure to ask your doctor to explain the risks and benefits of your treatment options and answer any questions you or your family may have. There are four basic treatment options for patients with carotid artery stenosis.

**Diet Modification and Exercise:** Decreasing the amount of fat and **cholesterol** in your diet in combination with exercise (especially 30 minutes of walking) in your daily activities may be recommended. Your doctor will make specific dietary and exercise recommendations for you. Other life style changes may also need to be made, including stopping smoking.

**Medical Management:** Your doctor may prescribe medicine to help thin your blood (**anticoagulants**), which will improve blood flow and help prevent your blood from clotting. Additionally, medications that help to lower your **cholesterol** and fats may be prescribed. If you have diabetes, your physician may change your medications to help reduce your blood sugar levels.

Both of the above options do not require any surgery, but each of them may not be enough to manage your disease completely. If neither of the above options is sufficient to manage your disease, one of the following interventional options may be recommended.

**Carotid Endarterectomy (Open Surgery):** This surgical procedure removes **plaque** from inside of your carotid artery in order to restore normal blood flow to your brain. You are usually put to sleep for this procedure using general anesthesia. The surgeon exposes your carotid artery through an incision (cut) in the side of the neck. The artery is clamped on both sides of the blockage and the artery is then opened. If the brain is not getting enough blood flow, a tube called a “shunt” may be placed around the blockage to keep blood flow during the procedure. The **plaque** inside of the artery is then removed and the artery is sewn back together. Sometimes, it is necessary to use a patch or graft when sewing the artery walls together to make the artery wider. As noted, this procedure requires general anesthesia and an incision in the neck, and as with any surgical procedure, has some risks. However doctors have been successfully conducting the procedure for over 50 years. Be sure to ask your doctor about the risks associated with this surgical procedure.

**Carotid Artery Angioplasty and Stenting with Distal Protection:** This procedure is presently available to you only if you have other conditions that place you at high risk for having problems during carotid endarterectomy (open surgery). The procedure involves placement of a **stent** into your carotid artery. A small incision is made in your groin or arm and small tubes or **catheters** containing the medical devices used for the procedure are inserted into the carotid artery in your neck. A filter basket is placed beyond the area of your blockage to help prevent any pieces of plaque or blood clots from traveling to your brain during the stenting procedure. A **balloon catheter** is then inflated to open the blockage. The **stent** is placed at the area of your blockage. The **stent** holds the artery open to allow normal blood flow to the brain. The **stent** is approximately  $\frac{3}{4}$  to 1-1/2 inches in length and  $\frac{1}{4}$  inch in diameter when expanded. You will remain awake during the stenting procedure. Please refer to “**Stent Implantation Procedure**” in this booklet for a more detailed description of the procedure. Carotid artery stenting does not require general anesthesia or an incision in the neck. It is a relatively new technique for treating carotid artery disease and does not have the long history of open surgery. However, a clinical study comparing stenting to surgery showed that the procedure is as safe and effective as surgery (see results below).

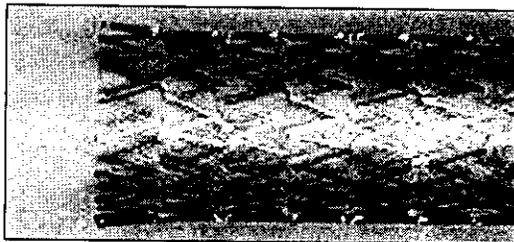
**Results of a Clinical Trial Comparing Open Surgery to Carotid Stenting:** A clinical study was conducted to compare carotid artery stenting to open surgery (carotid endarterectomy). In the study, 167 patients were treated with the stenting procedure and

167 patients were treated with the surgical procedure. There was no difference in the number of strokes, deaths or heart attacks between the two groups. The surgical group had a significantly higher number of **cranial nerve** injuries (nerves in the neck that control functions of speech, swallowing and facial movements). There were no such injuries in the stenting group because no incision is required in the neck. There were significantly more instances of low blood pressure and slow heart beat that required treatment in the stenting group. This is caused when pressure is applied to certain areas inside the carotid artery during the inflation of the balloon, or the expansion of the **stent** or filter basket.

### **CORDIS PRECISE NITINOL STENT SYSTEM**

**PRECISE Stents** are made of a metal called nitinol. The **stent** is inside a **sheath** (delivery system) for passage into the body to the **carotid arteries**, where it is released to hold open the blockage.

Cordis PRECISE Nitinol  
Stent

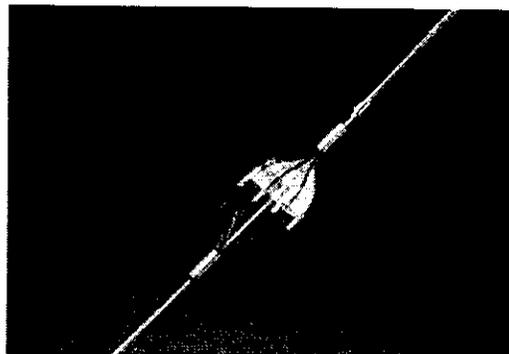


### **ANGIOGUARD XP EMBOLI CAPTURE GUIDEWIRE**

The **ANGIOGUARD XP Emboli** Capture Guidewire is a wire with a filter basket at the end for trapping particles during carotid artery stenting procedures.



ANGIOGUARD XP closed for delivery



ANGIOGUARD XP open during procedure

**PLEASE SEE THE SECTION CALLED "STENT IMPLANTATION PROCEDURE" FOR A PICTURE OF BOTH THE PRECISE STENT AND THE ANGIOGUARD DEVICES IN THE CAROTID ARTERY.**

## PREPARING FOR YOUR PROCEDURE

When **plaque** builds up in your **carotid arteries**, they begin to narrow and ~~slow down~~ blood flow to your brain. This is called **carotid artery stenosis**. Severe carotid artery **stenosis** is a major cause of stroke. The benefit of having **carotid artery stenting** is the reduction of **carotid artery stenosis**.

As with any intervention, the **angioplasty** and stenting procedure involves some risks. These risks include, but are not limited to:

- Stroke, heart attack, allergic reaction to the dye, slow heart beat which requires treatment, or death
- Rupture or damage to your carotid artery, excessive bleeding, infection/fever
- Bleeding bruising or swelling at the access (puncture) site in your groin or arm
- Failure to deliver the filter or **stent** to the site of your blockage (treatment failure)

Be sure that your doctor has discussed the procedure and the possible benefits and risks with you and that any questions you have are answered.

Upon admission to the hospital, you will have had tests such as carotid artery ultrasound, angiography and routine blood tests. Be sure to tell your doctor what medications you are currently taking and any allergies you might have. You will probably be asked not to eat or drink anything after midnight on the night before your procedure. You will be asked to take aspirin for one to two days before the procedure and your doctor may ask you to change other medications.

The procedure will be performed in a **catheterization** laboratory or a radiology suite. You will lie on a table, and an x-ray camera will pass over your body during the procedure. Your heart and blood pressure will be monitored during the course of the procedure.

The procedure will involve little to moderate pain and you will experience mild to moderate discomfort during the first few hours following the procedure. Dye injected through **catheters** will allow the doctor to see the area of blockage in your vessels. Although rare, dye may produce an allergic reaction causing low blood pressure and breathing difficulties

## STENT IMPLANTATION PROCEDURE

Your procedure will be performed in a room equipped with special instruments and x-ray equipment. Once you enter this room, you will be moved onto an x-ray table. You will be covered with sterile sheets and the area where the **catheter** will be inserted (groin or arm) will be shaved and washed with an antiseptic solution to prevent infection.

You will be awake during your procedure. Your doctor or a hospital member may give you instructions. It is important to listen for these instructions and do what is asked.

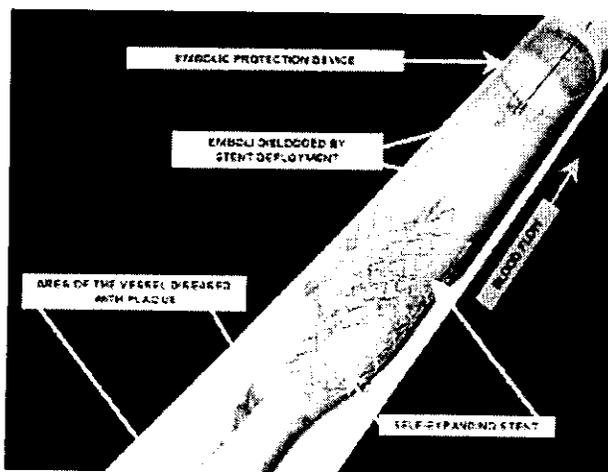
A numbing medication (**local anesthetic**) will be used at the site where the **catheter** is inserted. You may feel a stinging sensation when this medication is given. After the medication takes effect, you should only feel dull pressure where the doctor is working with the **catheters**. Where the groin or arm is cut, a small tube called a sheath will be inserted into your femoral artery (in your groin) or brachial artery (in your arm). The sheath provides a passageway through which the doctor can insert other necessary devices, such as **catheters**, the ANGIOGUARD XP Emboli Capture Guidewire, the PRECISE Nitinol **Stent** System, and balloons. Dye injected through **catheters** will allow the doctor to see the area of blockage in your arteries. An x-ray machine with a TV screen allows the doctor to see your arteries and any **catheters** that are moved in your arteries. Once your doctor has taken pictures of the blockage, the ANGIOGUARD XP is moved past the blockage and its filter basket is opened like an umbrella inside the artery. Then a **balloon catheter** is inflated. The balloon presses the **plaque** against the artery wall, causing the artery to open (this is called "PTA"). It is normal to experience some pressure during the balloon inflation. Please tell your doctor if you feel any pain during the procedure.

Inflated balloon catheter applying pressure to the vessel with plaque

Completed PTA of vessel lumen

The **stent** is then moved into the carotid artery on a delivery system and moved to the blocked area of the artery. The **stent** will open to fit the artery when it is released. One or more **stents** may be implanted. After the **stent** is placed, the delivery system is removed. Your doctor may further touch the **stent** with a **balloon catheter** to ensure that the **stent** is in full contact with the artery wall. The **stent** stays in place permanently, holding the artery open. After stent placement is completed, the ANGIOGUARD XP filter basket is closed and taken out of the body.

Your procedure will take approximately 60 to 90 minutes.



ANGIOGUARD XP and PRECISE Stent in the artery as the stent is being deployed from the catheter

## AFTER YOUR PROCEDURE

After the procedure, you will be moved to a special care unit where you will be closely monitored by the hospital staff. Your blood pressure and heart rhythm will be monitored continuously.

The sheath that was put in at the beginning of the procedure is usually removed at the end of the procedure, but may sometimes be left in place temporarily if your doctor feels it is necessary.

If your groin was used as an access site for the procedure, you will have to lie flat in bed and not move your leg for up to six hours, until your doctor tells you it is safe to do so. As the sheath is removed, the doctor or nurse will apply pressure to the puncture site for 20–30 minutes, until the bleeding has stopped. A sandbag may be placed over the puncture site to keep pressure on it. In some cases, the puncture site may be closed with a **closure device** that will be described to you by your doctor.

If your arm was used as an access site for the procedure, you may be allowed to sit up afterwards, but you may be asked to stay in bed for several hours. When the sheath is removed, the access site will be stitched closed.

While you are in the hospital, notify your doctor or other medical personnel if you feel lightheaded or dizzy, have trouble swallowing, have trouble seeing, or have blurry eyesight in one eye. Also notify them if you have weakness, numbness, or tingling or can't move your arm, leg, or face on one side of your body, or have unexplained slurred or garbled speech, or if you notice any bleeding from where the sheath was inserted.

## YOUR RECOVERY

Before you leave the hospital, your doctor will give you advice for activity, diet and medications. You will be asked to avoid hard activities like lifting for at least a week. You will be told when you can resume normal activity and return to work. Your doctor will prescribe medications for you to take to prevent blood clots from forming in your newly opened artery. Please notify your doctor if these medications cause unpleasant reactions. Do not stop taking them unless your doctor tells you to do so. Different medications may be prescribed that suit you better.

Patients who undergo **angioplasty** and **stent** implantation are usually discharged from the hospital the next day. You should arrange to have someone take you home rather than driving yourself. After you leave the hospital, it is important to keep all of your scheduled follow-up appointments so that your progress can continue to be monitored.

If you have any pain, discomfort or bleeding from where the sheath was inserted, call your doctor immediately. Also call your doctor immediately if you are lightheaded or dizzy, have trouble swallowing, have trouble seeing, or have blurry eyesight in one eye. Also notify your doctor if you have weakness, numbness, tingling or can't move your

arm, leg, or face on one side of your body, or have unexplained slurred or garbled speech. If your doctor cannot be reached immediately, call 911 to be taken to the nearest hospital emergency room.

After **stent** placement, you will be followed closely to monitor your recovery. An **ultrasound** will be performed to determine if any narrowing has occurred.

### **LIFESTYLE CHANGES**

You and your doctor have formed a team in an effort to reduce the risk of **restenosis** (re-occurring blockage) in the area of your **stent**.

To help stay healthy in the future, you are encouraged to make important diet, exercise, and lifestyle changes. Some patients may need few modifications while others may need to make many changes. It is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

### **STENT IMPLANT CARD**

Be sure your doctor gives you a completed "Stent Implant Card" that you can keep as a record of your procedure. Carry the card with you at all times and show it to any doctors or health care workers who may be treating you. The card will have the date of the **stent** procedure, location of the **stent** in your body, the name of the doctor who performed the procedure, and other important information.

### **IF YOU REQUIRE MAGNETIC RESONANCE IMAGING (MRI) AFTER CAROTID ARTERY STENTING**

If you require **MRI** after carotid artery stenting, tell your health care providers that you have a **stent** and show them your stent implant card, which will advise them to refer to the Cordis PRECISE Nitinol Stent System Instructions for Use at [www.cordislabeling.com](http://www.cordislabeling.com) or to call 1-800-372-7714 for more information about **MRI** compatibility of the PRECISE **Stent**.

### **CONCLUSION**

You have a very important role to play in order to ensure that your **stent** implantation is successful. It is essential that you cooperate with your doctor and follow through with your responsibilities as part of the patient/medical team. Keep your appointments, a healthy lifestyle, and continue to follow your doctors' advice with respect to any other medical conditions that you are being treated for. If you have any questions or concerns, please contact your doctor to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with vascular disease who are leading healthy, productive lives.

## GLOSSARY

<b>Angiogram</b>	A procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.
<b>Angioplasty</b>	A procedure whereby a balloon dilation <b>catheter</b> is passed through the blood vessel to the blocked area of an artery. Once the balloon on the tip of the <b>catheter</b> is inflated, the blocked area in the artery is opened. Also called <b>PTA</b> (Percutaneous Transluminal <b>Angioplasty</b> ).
<b>Anticoagulant</b>	A medicine that slows or prevents the clotting of blood.
<b>Atherosclerosis</b>	The process of fatty deposits and/or calcium build-up ( <b>plaque</b> ) on the inside of the arteries.
<b>Balloon Catheter</b>	A long tube that passes through your arteries with a tiny balloon on its tip. The balloon is inflated after it is in place to open a blockage and press the <b>stent</b> against the artery wall.
<b>Bradycardia</b>	Slow heart beat, possibly requiring need for a temporary or permanent pacemaker.
<b>Carotid Arteries</b>	Arteries are vessels that carry blood away from the heart. The <b>carotid arteries</b> extend from the main artery (aortic arch) coming directly from the heart and supply oxygen-rich blood to the brain.
<b>Catheter</b>	A long hollow tube used to introduce a device, drug, or dye into a blood vessel.
<b>Catheterization</b>	A procedure that involves passing a tube ( <b>catheter</b> ) through blood vessels and injecting dye to detect blockages.
<b>Cholesterol</b>	A substance that circulates in the blood and when deposited in the artery, plays a role in the formation of blockages. <b>Cholesterol</b> originates in foods that are rich in animal fat.
<b>Closure Device</b>	After completion of the procedure, a <b>closure device</b> is used at the puncture site to stop the bleeding.
<b>Cranial Nerve</b>	Nerves in the neck that control functions of speech, swallowing and facial movements.
<b>Emboli</b>	Small clots or pieces of <b>plaque</b> that travel in the bloodstream and lodge in a blood vessel, blocking blood flow.
<b>Lesion</b>	A blockage in a blood vessel. Also known as a <b>plaque</b> or stenosis.
<b>Local Anesthetic</b>	A substance used to numb the area to which it is applied.

<b>MRI (Magnetic Resonance Imaging)</b>	A diagnostic test that uses magnetic waves to obtain images of the inside of your body.
<b>Plaque</b>	An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the artery.
<b>PTA (Percutaneous Transluminal Angioplasty)</b>	A procedure performed through a small opening in the skin whereby a balloon dilation <b>catheter</b> is passed through the blood vessel to the blocked area of an artery. Once the balloon on the tip of the <b>catheter</b> is inflated, the blocked area in the artery is opened. PTA is also call <b>Angioplasty</b> .
<b>Restenosis</b>	The recurrence of a narrowing or blockage in an artery after treatment.
<b>Stent</b>	An expandable, metallic, tubular shaped device that provides structural support for a vessel.
<b>Stenosis</b>	A narrowing in your arteries caused by plaque build-up, which restricts blood flow.
<b>Ultrasound</b>	A non-invasive test using sound waves to determine the presence of arterial narrowing.

## CONTACT INFORMATION

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.

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